XIII. 510(k) Summary

NOV 2 7 2001

SUBMITTER: DePuy AcroMed, Inc.
325 Paramount Drive
Raynham, MA 02780

CONTACT PERSON: Lisa A. Gilman

DATE PREPARED: August 22, 2001

CLASSIFICATION NAME: Spinal Intervertebral Body Fixation Orthosis

PROPRIETARY NAME: Frontier Anterior Scoliosis System

PREDICATE DEVICES: MOSS MIAMI Spinal System (K953915)
KANEDA™ Anterior Scoliosis System (K974757)
CD HORIZON® ECLIPSE™ (K001066)

DESCRIPTION: The FRONTIER Anterior Scoliosis System consists of spinal rods, spinal screws, spinal staples, and spinal washers. The implants of the FRONTIER Anterior Scoliosis System have been designed for use in either open or thoracoscopic approaches.

INTENDED USE: The FRONTIER Anterior Scoliosis System is intended for anterolateral screw fixation to the T4 to L4 levels of the spine, with all metal at least 1 cm from a major vessel. The FRONTIER Anterior Scoliosis System may be used in either thoracoscopic procedures or open procedures.

The FRONTIER Anterior Scoliosis System is intended to provide temporary stabilization as an adjunct to spinal bone grafting processes. Specific indications are:

1. Idiopathic scoliosis.
2. Degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies).
3. Scoliosis with deficient posterior elements such as that resulting from laminectomy or myelomeningocele.

4. Neuromuscular scoliosis/kyphoscoliosis.
5. Spinal fractures (acute reduction or late deformity).
6. Revision surgery.
7. Tumor.

The FRONTIER Anterior Scoliosis System can also be used for the correction and stabilization of scoliotic curves, for the prevention or recurrence of undesired scoliotic curves, and for the stabilization of weakened trunks. Indications for these scoliotic uses include:

1. Collapsing and unstable paralytic deformity.
2. Progressively increasing scoliosis.
3. Decreasing cardio-respiratory function, secondary to spinal or rib deformity or collapse.
4. Inability to maintain sitting balance, necessitating the use of hands.
5. Increasing pelvic obliquity coincident with back pain or loss of sitting balance.

MATERIALS:

Manufactured from ASTM F-136 implant grade titanium alloy.

PERFORMANCE DATA:

Performance data were submitted to characterize the FRONTIER Anterior Scoliosis System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 7 2001

Ms. Lisa Gilman
Regulatory Affairs Associate
DePuy Acromed, Inc.
325 Paramount Drive
Raynham, Massachusetts 02767-0350

Re: K012916
Trade/Device Name: FRONTIER™ Anterior Scoliosis System
Regulatory Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: II
Product Code: KWQ
Dated: August 29, 2001
Received: August 30, 2001

Dear Ms. Gilman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K012916

IV. Indications for Use

510(k) Number (if known): K012916

Device Name: FRONTIER™ Anterior Scoliosis System

Indications For Use:
The FRONTIER Anterior Scoliosis System is intended for anterolateral screw fixation to the T4 to L4 levels of the spine, with all metal at least 1 cm from a major vessel. The FRONTIER Anterior Scoliosis System may be used in either thoracoscopic procedures or open procedures.

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for (Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K012916

(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: Y OR Over-The-Counter Use: _____
(Per 21 CFR 801.109)